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A Population-Based Study of Variation In and Outcomes of Care

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<b>13. ABSTRACT (Maximum 200)</b>  We have utilized SEER and Medicare data bases to study patterns of care related to the treatment of local/regional breast cancer. In analyzing the generalizability of the population covered by SEER, we have determined that the SEER population is more affluent, has lower unemployment, and is substantially more urban than the rest of the United States. There factors must be considered in generalizing to the rest of the U.S. Our initial studies of a cohort of 4341 patients aged 65 and older who received surgical treatment for early breast cancer, and had coverage with parts A and B of Medicare have revealed the following. Most patients (74%) received mastectomy treatment, and the remainder (26%) received breast-conserving treatment. Only 44% of the patients received mammography in both of the first two years of surveillance after initial treatment. About 30% did not have a mammography claim in either surveillance year. Mammograms were less likely to be received by African-American women, by women undergoing mastectomy treatment, and by women with regional stage disease. The median number of office visits for cohort patients was 6 per year. On average, patients saw 2.5 different types of providers annually.				
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Part 4.

**TABLE OF CONTENTS**

	<b><u>PAGE NUMBER(s)</u></b>
FRONT COVER	1
SF 298, REPORT DOCUMENTATION PAGE	2
FOREWARD	3
TABLE OF CONTENTS	4
INTRODUCTION	5-6
BODY	6-18
CONCLUSIONS	19
REFERENCES	20
APPENDICES	21
1.) <u>Manuscript:</u> Generalizability of the surveillance, epidemiology, and end results registry population: Factors relevant to health services research.1996, submitted.	
2.) <u>Reprint:</u> The effect of legislative requirements on the use of breast- conserving surgery. <u>N Engl J Med</u> 1996;335(14):1035- 1040.	
3.) <u>Abstract:</u> Rates of surveillance testing and office visits after initial treatment for early stage breast cancer. Podium presentation, Regional Society for General Internal Medicine Meeting, Chicago, Illinois, September, 1996.	

## **Part 5.      INTRODUCTION**

The overall goal of this research is to utilize secondary data bases (tumor registry, claims data and census data) to describe practice patterns, and limited outcomes, for older women with local or regional breast cancer. Our previous studies have described variation in surgical treatment of local and regional breast cancer. Specifically, we have documented substantial geographic variation in the use of breast-conserving surgery, as opposed to mastectomy in the treatment of local and regional breast cancer.<sup>(1,2)</sup> Breast-conserving surgery is much more likely to be utilized in the Northeast, and along the West coast of the country. We have also documented that breast-conserving surgery was adopted earlier in urban vs rural hospitals. The use of breast-conserving surgery is also greater in larger, higher volume teaching facilities, and facilities with radiation therapy and geriatric services available. Our previous studies of patient factors<sup>(3)</sup> have shown that the use of breast-conserving surgery is greater for women living in areas of the country with higher median income, and higher educational status. The use of breast-conserving surgery is lower in African-American women, but this finding appears to be attributable to socioeconomic factors.

The focus of the current grant is to extend our previous work on variation and practice patterns. Specifically, we are utilizing the SEER National Tumor Registry data, and a file of Medicare claims which have been linked to SEER female patients with regional or local breast cancer who are aged 65 and greater. After assembling a cohort of SEER patients who have received breast-conserving

surgery or mastectomy treatment for early breast cancer, we are utilizing the cohort to 1.) describe the use of medical resources after initial treatment for the breast cancer, 2.) relate the use of these resources to patient and hospital characteristics and 3.) determine whether an association exists between patterns of intensity in resource use and the outcomes of a.) inpatient hospital days associated with a diagnosis of metastatic cancer, and b.) death from breast cancer.

## **Part 6.      BODY**

### Generalizability of SEER

The SEER-Medicare linked data base is a relatively new resource for health care researchers (4), and we needed to assess the generalizability of our analyses derived from this data base to the rest of the country . We utilized the federal Area Resource File (ARF), to compare the population of the 198 SEER counties to the population of the 2882 non-SEER counties regarding demographic factors, physician availability, and availability of pertinent hospital resources (see manuscript in appendix).

We found that the SEER population is more affluent, has lower unemployment, and is substantially more urban than the remainder of the U.S. population ( $p < 0.001$  for each). The SEER areas have a lower density of general and family practice physicians, but a higher density of total non-federal physicians, general internists, and specialists relevant to cancer care. The SEER areas have fewer JCAH-accredited hospitals, hospital beds, and hospitals with CT scanners, but more hospitals with bone marrow transplantation.

To further assess the generalizability of SEER-based studies involving black patients, we compared the characteristics of SEER counties with at least 5% of black population to the characteristics of non-SEER counties with at least 5% black population. We found an even greater discrepancy between SEER and non-SEER counties in terms of per capita income and educational status. In addition, the SEER areas with at least 5% black population are heavily concentrated in urban sites. Rural representation of black patients is almost missing. Other findings regarding physician and hospital resources generally paralleled the overall results for the entire country.

We conclude that the differences between the SEER population and the remainder of the United States, especially SEER's higher socioeconomic status in more urban population, should be considered when generalizing from SEER patients to the entire country.

#### Legislative Requirements

To better understand the factors which influence the surgical treatment of women with early breast cancer, we studied the effect of state legislation requiring the disclosure of options for the treatment of breast cancer on the use of breast-conserving surgery (5, reprints in appendix) . Since the use of breast-conserving surgery is a probable predictor of surveillance resource use, it is important to understand the factors associated with use of this newer treatment.

We utilized the SEER registry to provide data on women aged 30-79 years who underwent breast-conserving surgery or



mastectomy for local or regional breast cancer from 1983-1990. We examined the temporal trend in the use of breast-conserving surgery among patients in the four SEER sites (Connecticut, Iowa, Seattle, and Utah) where there were no state laws specifically requiring the disclosure of options for the treatment of breast cancer. For four additional SEER sites (Detroit, Atlanta, New Mexico, and Hawaii) that had enacted relevant legislation during the 1980's. We determined whether the rate of use of breast-conserving surgery after the legislation differed from the expected rate.

An attorney rated the legislation as being most directive of physicians in Michigan, followed by Hawaii, Georgia, and then New Mexico. The rate of breast-conserving surgery was up to 8.7% higher than expected in Detroit for 6 months after the passage of the Michigan law ( $p < 0.01$ ). The rate was up to 13.2% higher than expected in Hawaii for 12 months after that state's law was passed ( $p < 0.05$ ), and up to 6% higher than expected in Atlanta for 3 months after the passage of the passage of their Georgia law ( $p < 0.01$ ). After these transient increases, the breast-conserving surgery rates reverted to the levels expected, based on the temporal trend. No significant effect was detected in New Mexico, where only a resolution without legally binding stature was passed.

We conclude that legislation requiring physicians to disclose surgical options for the treatment of breast cancer appear to have only minimal and transient effect on the rate of use of breast-conserving surgery.

### Use of Surveillance Tests

We have assembled a cohort of SEER patients for whom linked Medicare claims data are available, and we are in the process of describing the use of surveillance testing in this group of patients (abstract in appendix). The objectives are to 1.) describe the use of surveillance testing with mammography, chest x-ray, bone scan, and office visits in the Medicare population after initial surgical treatment for early stage breast cancer, and 2.) describe the socioeconomic, clinical, and demographic associations with the use of surveillance testing.

The data bases used for these analyses include the national SEER data for 5 entire states and 4 metropolitan regions, the linked Medicare data claims from the Part-A hospital file for 100% of patients, and the Part-B physician billing records for a fraction of the patients, and a 1990 census data by zip code.

Figure 1 clarifies the development of the clinical cohort for study. Patients were ineligible for this analysis if they did not receive surgical therapy, if they could not be linked to Medicare files, or if they died within 12 months of the month of diagnosis. In addition, we required that they be eligible for Parts A & B of Medicare for 3 years from the date of diagnosis, or until the date of death. We also required that the patient not belong to an HMO during the study period, as specific claims information is not available for patients belonging to an HMO. For patients who were diagnosed during the 1980's, Part-B data was available for a random sample of 5% of the entire cohort, and additionally for 100% of patients treated in 3 of the SEER areas. The final study cohort consisted of

4,341 patients, who were women aged 65 years and older, with a first breast cancer diagnosis in the years 1985-87, who had received either breast-conserving surgery or mastectomy treatment and had appropriate Medicare data available.

The information on the distribution of the patient cohort in terms of demographics, comorbidity, and treatment is presented in Table 1. Note that the mean per capita income and educational status figures are derived ecologically from the census data based on the zip code of residence of the patients.

The definition of the periods of surveillance is presented in Table 2. Note that surveillance year 1 commences at 6 months after the month of diagnosis, (based on the SEER Tumor Registry information). Because patients undergoing surveillance would be expected to have repetitive testing, the category of "annual surveillance" was developed to include subjects who received a given test in both surveillance year 1 and year 2.

The percentage of the cohort receiving mammography, chest x-ray, or a bone scan in selected surveillance years is presented in Table 3. Periodic mammography is generally recommended by all authorities. In our cohort 44% of the subjects had a claim for a mammogram in both surveillance years 1 and 2. Twenty-six percent had a claim for a mammogram in surveillance year 1 or year 2, and 30% had no claims for surveillance mammograms. The use of chest x-rays in this cohort generally paralleled the use of mammograms, although only 20% of the patients did not undergo a chest x-ray in either surveillance year. The majority of women did not undergo a bone scan in either year, despite the fact that some authorities had

recommended this as appropriate surveillance testing during the 1980's and early 1990's.

Initial univariate associations of some patient factors with the use of annual mammography surveillance are presented in Table 4. Mammograms were less likely to be received by African-American women, by women undergoing mastectomy treatment, and by women with regional stage disease. In addition, women undergoing less than annual mammography had higher average comorbidity scores (calculated for the purposes of this analysis as the sum of the number of diagnostic codes during the treating hospitalization). Women undergoing less than annual mammography lived in zip codes with lower per capita incomes, and lived in areas where a larger percentage of the population had failed to complete 4 years of high school.

Some early descriptive information regarding receipt of office visits by cohort patients is provided in Table 5. Study subjects had a median of 6 office visits per year. These office visits were provided by approximately 2.5 different types of providers each year. The most common provider types utilized by cohort patients were internal medicine, followed by general surgery, and general practice or family medicine. The analysis of provider type is limited as many visits are coded only as "multispecialty clinic", and the specific provider specialty cannot be determined.

In summary, we have found that only about 44% of women with diagnosed breast cancer received annual surveillance with mammography. The pattern of use of chest x-rays was similar to the pattern of use of annual surveillance mammography, despite the

relative paucity of evidence of benefit of annual chest x-rays. The use of bone scan was much lower in this study cohort. Women were more likely to receive annual mammography surveillance if they were younger, healthier, of white race, treated with breast-conserving surgery, or had less extensive disease at diagnosis. Women in this cohort underwent a median of 6 office visits per year, and on average, saw 2.5 different types of providers.

This study has the limitation of the possibility of incomplete ascertainment of Medicare Part-B outpatient data. Note, however, that Medicare did pay for mammography in breast cancer survivors at the time of this study. Furthermore, the high number of office visits found in the study cohort suggests that subjects were receiving outpatient care that was captured in the Medicare data base. A second limitation is the inability to differentiate surveillance testing from testing done for other reasons. We are presently proceeding with analyses to determine what percentage of chest x-rays were completed during the course of an acute care hospitalization.

We conclude that our early findings suggest underutilization of mammography surveillance in women with breast cancer, particularly in African-American and poorer populations. The use of chest x-ray was relatively high, despite the lack of efficacy of this test. We are presently obtaining more recent Medicare data to determine the use of surveillance tests through 1994. We are also proceeding with further analyses to delineate the relationship of surveillance testing to morbidity and mortality outcomes in women after treatment of breast cancer.

FIGURE 1.

### Cohort Development

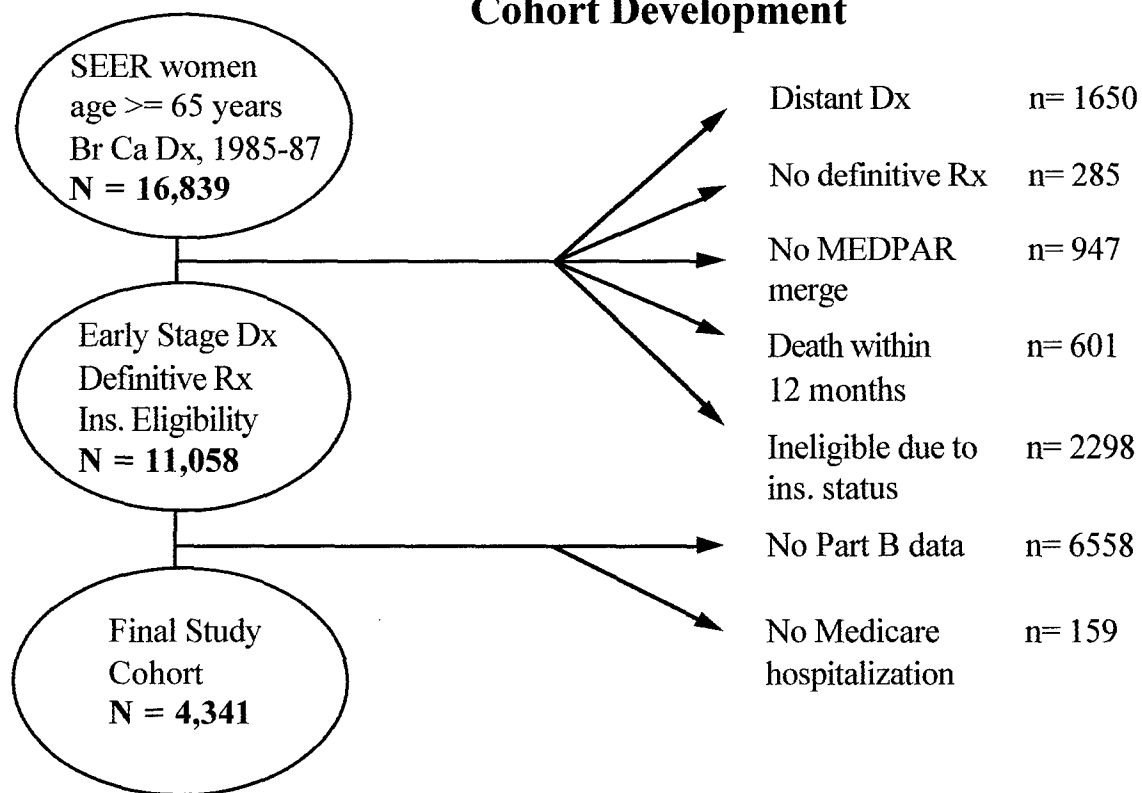


TABLE 1.

# Results

(n = 4341)

- |  |   |
|--|---|
| <ul style="list-style-type: none"> <li>• Age               <ul style="list-style-type: none"> <li>– Mean 74.0 (SD 6.71)</li> </ul> </li> <li>• Race               <ul style="list-style-type: none"> <li>– Caucasian 95.16%</li> <li>– African-American 4.03%</li> </ul> </li> <li>• Comorbidity               <ul style="list-style-type: none"> <li>– Mean 2.6 (SD 1.4)</li> </ul> </li> </ul> | <ul style="list-style-type: none"> <li>• Treatment               <ul style="list-style-type: none"> <li>– Mastectomy 76.98%</li> <li>– BCS 23.91%</li> </ul> </li> <li>• Mean Per Capita Income               <ul style="list-style-type: none"> <li>– \$8613 (SD 2539)</li> </ul> </li> <li>• &lt; 4 yr high school               <ul style="list-style-type: none"> <li>– 26.42% (11.80)</li> </ul> </li> </ul> |
|--|---|

TABLE 2.

## Definition of Surveillance Test Periods

- *Surveillance Year 1:* A test occurring between 6 and 18 months after the date of diagnosis.
- *Surveillance Year 2:* A test occurring between 18 and 30 months after the date of diagnosis.
- *Annual Surveillance:* Subject has a given test in surveillance years 1 and 2.



TABLE 3.

Surveillance Practice Patterns			
<u>Test</u>	<u>Annual</u>	<u>One Year</u>	<u>None</u>
Mammography	44%	26%	30%
Chest X-ray	44%	36%	20%
Bone Scan	10%	22%	68%

TABLE 4.

## Annual Mammography Surveillance

- Race
  - Caucasian 44%
  - African-American 24% \*
- Treatment
  - Mastectomy 42%
  - BCS 47% \*
- Stage
  - In situ 52%
  - Localized 44%
  - Regional 40% \*

\*  $p < 0.05$

TABLE 5.

## Office Visits

- Median visits (years 1 and 2) 6 / yr
- # providers/year (mean, sd)
  - Surveillance year 1 2.4 (1.1)
  - Surveillance year 2 2.6 (1.3)
- Provider Type (years 1 and 2)
  - Internal Medicine 32.9%
  - General Surgery 15.0%
  - General Practice, FM 14.1%

**Part 7.      CONCLUSIONS**

Final conclusions are pending completion of the above-detailed research in progress.

**Part 8.      REFERENCES**

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4.    Potosky AL, Riley GF, Lubitz JD, Mentnech RM, Kessler LG Potential for cancer related health services research using a linked Medicare-Tumor Registry database. Med Care 1993;31:732-748.
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**Part 9.      APPENDICES**

- 1.) Nattinger AB, McAuliffe TL, Schapira MM. Generalizability of the surveillance, epidemiology, and end results registry population: Factors relevant to health services research. 1996, submitted.
  
- 2.) Nattinger AB, Hoffmann RG, Shapiro R, Gottlieb MS, Goodwin JS. The effect of legislative requirements on the use of breast-conserving surgery. N Engl J Med 1996;335(14):1035-1040.
  
- 3.) Schapira MM, McAuliffe TL, Nattinger AB. Rates of surveillance testing and office visits after initial treatment for early stage breast cancer. Podium presentation, Regional Society for General Internal Medicine Meeting, Chicago, Illinois, September, 1996.

Generalizability of the Surveillance, Epidemiology, and End Results Registry Population:  
Factors Relevant to Epidemiologic and Health Care Research

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## ABSTRACT

Generalizability of the Surveillance, Epidemiology, and End Results Registry Population:  
Factors Relevant to Epidemiologic and Health Care Research

Running Head: Generalizability of SEER

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To assess the generalizability of the population included in the Surveillance, Epidemiology, and End Results (SEER) tumor registries to the overall United States population, we compared the population of the 198 SEER counties to the population of the 2882 non-SEER counties regarding sociodemographic factors, physician availability, and availability of pertinent hospital resources.

The SEER population is more affluent, has lower unemployment, and is substantially more urban than the remainder of the U.S. population ( $p < 0.001$  for each). The SEER areas have fewer general and family practice physicians, but more total nonfederal physicians, general internists, and specialists relevant to cancer care. SEER areas have fewer JCAH-accredited hospitals, hospital beds, and hospitals with CT scanners, but hospitals with bone marrow transplantation.

The differences between the SEER population and the remainder of the U.S., especially SEER's higher socioeconomic status and more urban population, should be considered when generalizing from SEER to the entire country.



Key Words: Cancer, Tumor Registry, Health Services Research, Clinical Epidemiology.

## INTRODUCTION

In recent years, it has been recognized that non-clinical factors function as important predictors of patterns of clinical practice and of the outcomes associated with cancer care [1]. For example, a number of non-clinical determinants of treatments and outcomes for breast cancer patients have been described, including geographic location [2, 3], patient age [4-6], race and socioeconomic status [7-9], insurance status [10], and hospital factors, including volume of cases and urban vs rural status [2,11,12].

One source of information regarding practice patterns for cancer patients has been the Surveillance, Epidemiology, and End Results (SEER) program of the National Cancer Institute. The SEER program includes a group of 9 population-based tumor registries which gather information on about 10% of the patients in this country with cancer [13]. Although SEER is intended primarily as a source of cancer incidence and mortality rates in the United States, information gathered by SEER has been used as the basis for several analyses regarding patterns of cancer treatment [3, 4, 14-16].

It is recognized that the population of potential subjects included in SEER is not a random subset of the United States population [17]. For instance, the SEER population was designed to oversample less common minority populations, to permit inclusion of sufficient numbers for analysis. However, to the extent that non-clinical factors influence treatments for and outcomes of cancer patients, the non-random nature of the SEER population must be considered when generalizing from SEER to the rest of the United States. The goal of this report is to compare the population residing in the geographic areas included in the SEER cancer registries to the population in the rest of the United States, regarding factors which may affect the delivery of cancer-related health care, or outcomes of patients with cancer. Investigators studying patients in the SEER database could then use this

information for analytic adjustments, or at least to determine the direction in which the SEER sample might be expected to deviate from the overall U.S. population with respect to the treatment pattern or outcome of interest.

## METHODS

### Source of Data

Since the SEER population coverage areas are demarcated by county borders, we chose the 1992 Area Resource File [18] as a source for data on the SEER vs non-SEER populations. This file is a federally maintained county-level compilation of demographic, socioeconomic, and environmental factors, which also provides information on the availability of many health care resources.

### Factors Studied

The information identified was chosen based on known or suspected predictors of cancer treatments or outcomes, and included the 1990 county age and race distributions, urban vs rural status (size of metropolitan statistical area), per capita income, educational status, and unemployment rate. Information on various types of physicians relevant for cancer diagnosis and treatment included numbers of family practitioners, general internists, medical and surgical specialists, obstetrician-gynecologists, radiation oncologists, and medical oncologists. Information on hospital-based resources located within each county included numbers of JCAH-accredited hospitals, teaching hospitals, hospital beds, and the number of hospitals providing various services relevant for cancer care (CT and MRI scanners, radiation therapy services, bone marrow transplantation, outpatient surgery, home health services, and hospice services).

### Statistical Analysis

A county-level analysis plan was used, since information at the county-level was available regarding a variety of factors of interest, and since SEER population areas are demarcated by county borders. The 3080 U.S. counties were divided into the 198 counties for which SEER collects cancer information, and the 2882 counties not covered by the SEER program. The 9 SEER sites are quite heterogeneous regarding number of counties (Table 1). The counties also vary widely in total population. Therefore the number of counties at each SEER site is not indicative of the percentage of the total population contributed by that site (Table 1).

Due to the variability in county total population, we have chosen to present estimated health services resource availability in the form of density per 100,000 population. Weighted least-squares analysis is used to compare SEER vs non-SEER counties, with weight equal to total population of the county. Weighted least-squares can be used to correct for heterogeneity of variance, as is the case for the density estimates which depend on the total population of the county. A second benefit of weighting by total population of the county is that the density estimates for counties with larger populations receive greater weight in the overall density estimates comparison, while the smaller counties receive less weight in this overall comparison. All analyses were performed using the SAS statistical software [19]. In order to maintain an overall significance level of 0.05 when performing approximately 50 comparisons, a p-value of less than 0.001 is considered significant. This criterion corresponds to a Bonferroni adjustment.

To estimate the statistical accuracy of the weighted least-squares estimates we used a bootstrap approach and the percentile interval method [20] to estimate a 95% interval for the true weighted means. These 95% intervals extend from the 2.5th to the 97.5th percentile of the bootstrap distribution of the weighted least-squares estimate. This approach was used

because these resource data are often characterized by heavy skewness as well as a large number of counties having no hospital resources or specific MD resources. In these situations the standard symmetric confidence interval for a population mean can be quite inaccurate. The usual power transformations to overcome skewness have no effect on the problem created by the discontinuity in the resource distribution with a large probability at zero.

As the national SEER data base has been utilized in the analysis of treatment patterns for persons of black race [4, 14], we made further comparisons using the subset of counties with at least 5% black population. There are 1054 such U.S. counties, of which 20 are included in the SEER program. We compared the SEER and non-SEER counties within this subset regarding the same group of sociodemographic, physician, and hospital factors.

## RESULTS

### Sociodemographic factors

There are 198 counties for which the SEER program gathers data, and these counties had a total population of 23,553,609 persons in 1990. Overall  $10.82\% \pm 0.75\%$  of the population of SEER counties are of black race, compared to  $12.18\% \pm 0.75\%$  of all other U.S. counties ( $p = 0.08$ ). Overall  $79.07 \pm 0.91\%$  of the population of SEER counties are of white race, compared to  $80.52 \pm 0.29\%$  of all other U.S. counties ( $p = 0.01$ ).

Within the 9 SEER sites, the racial distribution varies substantially (Table 1). As mentioned above, several of the SEER sites were selected in order to provide epidemiologically significant numbers for racial subgroups [17]. The black population captured by SEER is located mainly in the Atlanta, Detroit and San Francisco metropolitan sites, and the state of Connecticut (Table 1). The San Francisco, Hawaii, Seattle, and New

Mexico sites provide relatively high proportions of Asians, Hispanics, and/or Native Americans.

The age distribution of the adult population living in the 198 SEER counties is slightly younger than the age distribution of the adult population living in the 2882 other U.S. counties. The age group 0-19 years accounts for 21.2% of the SEER population compared to 21.4% of the non-SEER population ( $p = 0.10$ ). The age group 20-34 years accounts for 25.4% of SEER and 25.0% of non-SEER ( $p = 0.003$ ). The age group 35-54 accounts for 26.2% of SEER compared to 25.1% of the non-SEER population ( $p < 0.001$ ). The age group 55-64 accounts for 8.1% of SEER, compared to 8.5% of non-SEER ( $p = 0.001$ ), and the age group 65 and older accounts for 11.7% of SEER population, compared to 12.6% of the non-SEER population ( $p = <0.001$ ). Similar results were found for comparisons stratified by gender (results not shown). Although several of these differences achieve statistical significance, they are quite small. Since virtually all analyses include adjustment for patient age, these differences in age distribution would seem unlikely to be important for most studies.

Overall, the population living in SEER counties is wealthier and has lower unemployment than the population living in other U.S. counties (Table 2). A higher percentage of the SEER population has completed high school. There is no difference between SEER and other counties in the percentage of owner-occupied housing units. The SEER population is substantially more concentrated in urban locations, and much less concentrated in rural locations, compared to the rest of the United States (Table 2).

### Physician Resources

SEER counties generally have larger numbers of physicians per 100,000 population, with more nonfederal physicians, medical specialists, general internists, and obstetrician-

gynecologist physicians (Table 3). SEER counties have marginally more surgical specialists and radiation oncologists. SEER counties trend toward having fewer general practitioners and family physicians, and there was no difference between SEER and other counties in the number of board certified oncologists. For some of the physician resource measures, counts were available broken down by categories of patient care or teaching practice. These measures gave similar results, so only analyses using total physicians are presented in Table 3.

#### Hospital Resources

SEER and non-SEER counties were also compared regarding the availability of various hospital-based resources (Table 4). SEER counties have significantly fewer hospitals with JCAH accreditation, fewer short term general hospital beds, community hospital beds, general medical/surgical beds set up, and fewer hospitals with CT scanners. SEER counties trend toward fewer hospitals with outpatient surgery, and do not differ from the rest of the U.S. counties with regard to hospitals with radiation therapy, home health services, hospice services, or MRI scanners. SEER counties have significantly more hospitals with bone marrow transplantation, and marginally more hospitals with residency training programs.

#### Counties With $\geq 5\%$ Black Population

Since patient information collected by SEER is sometimes used for analyses involving race, especially black race, further analyses were done of the 20 SEER counties with at least 5% black population, compared to the 1034 other U.S. counties with at least 5% black population. The SEER counties with at least 5% black population have a substantially higher per capita income than do other U.S. counties with at least 5% black population, and they have a higher educational status (Table 2). However, there was less difference in the unemployment rates, and no difference in the percent of owner-occupied housing. SEER

counties with at least 5% black population have essentially no rural representation, and virtually all of these counties are in highly urban metropolitan areas (Table 2).

SEER counties with at least 5% black population trend toward fewer general practitioners and family physicians, but trend toward having more total physicians, medical specialists, general internists, and obstetrician-gynecologists (Table 3). The SEER counties with at least 5% black population have fewer hospitals, fewer short term hospital beds, fewer hospitals with CT scanners, and fewer hospitals with outpatient surgery facilities. (Table 4). In general the results for the counties with at least 5% black population parallel the overall results, but SEER vs non-SEER differences are even greater regarding income and urban vs rural representation.

## DISCUSSION

In this report, we have demonstrated how the population included in the SEER tumor registry system differs from the population of the remainder of the counties in the United States. Specifically, the SEER population is more affluent, more highly educated, has a lower unemployment rate, and is substantially less rural than the remainder of the U.S. The SEER population areas tend to have a lower density of general and family practice physicians, but a greater density of general internists, as well as medical and surgical specialists relevant to cancer care. The SEER population areas have fewer hospital resources as measured by several types of beds, and fewer hospitals with CT scanners, but a slightly greater density of hospitals with bone marrow transplantation facilities. SEER counties with at least 5% black population are much wealthier, better educated, and more urban than other U.S. counties with at least 5% black population. These counties also have fewer general practitioners and family physicians, more specialist physicians, fewer hospital beds, fewer hospitals with CT scanners and fewer hospitals with outpatient surgery facilities.



The national SEER registry is sometimes utilized as though it were representative of the U.S. population [17]. However, as demonstrated above, there are differences between SEER and the remainder of the U.S. that are not addressed by simple adjustment for gender and age distributions. These differences may manifest as a potential source of bias for several types of studies. It has been reported that the distribution of socioeconomic status in SEER patients may have lead to an overestimate of the national breast cancer incidence and mortality estimates [21], since patients of higher socioeconomic status have a higher incidence of breast cancer. Patients included in SEER have also been used as a population-based source of controls for technology assessment studies [22], but bias could be introduced by the fact that SEER patients are not entirely representative of the entire U.S. in terms of socioeconomic status, urban vs rural residence, physician, or hospital resources.

Many studies of interest to epidemiology and health care researchers report patterns of clinical practice, and outcomes associated with these patterns. The present results imply that caution should be taken in generalizing findings from the SEER population to the rest of the country. For example, we have shown that Medicare patients with early stage breast cancer are more likely to undergo breast-conserving surgery if treated in more urban hospitals [2], or if they are of higher socioeconomic status [23]. Since the SEER data base includes an over-representation of both urban and higher socioeconomic status patients, one would predict that the rate of use of breast-conserving surgery in SEER patients would be higher than the use in the rest of the country.

One potential way of dealing with the problem of generalizability of the SEER population with regard to sociodemographic factors is to use proxy census information to adjust for such factors analytically [24]. For instance, the SEER public use file contains the county of residence of each patient, which permits assigning the size of the metropolitan statistical

area in which the patient resides and some proxy socioeconomic information. Adjusting for sociodemographic factors may remove much of the SEER vs non-SEER difference in physician and hospital factors [21], but it would be advisable to tailor adjustment for these covariates to the specific study question.

The findings detailed in this study do not negate the importance of the SEER data base as a resource for the study of cancer-related health care. The SEER data base is population-based within the 198 counties included in it. It includes excellent representation of all age groups and both genders. The information on extent of disease is much more detailed than such information in most claims or administrative data bases. The information on stage of disease and initial treatment is of verified accuracy.

However, the limitations of the SEER data base must also be considered by health care researchers contemplating its use. As reported in this paper, the generalizability of the data base must be considered. No information is included on comorbid illnesses or diagnoses in addition to the cancer diagnosis, an omission which is especially relevant for studies of older patients. Also, no follow-up information is included, except for death and cause of death. A linkage of SEER and Medicare data for SEER patients ages 65 and older has been carried out, and may permit some assessment of comorbidity and follow-up for older patients [25].

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**TABLE 1**  
**Counties Included in SEER Database**

<u>Site</u>	<u>Counties</u>	<u>% SEER</u> <u>Counties</u>	<u>Total</u> <u>Population</u>	<u>% SEER</u> <u>Population</u> <sup>¶</sup>	<u>% Black</u> <sup>§</sup>	<u>% White</u> <sup>§</sup>	<u>% Other</u> <sup>§</sup>	<u>% Hispanic</u> <sup>¥</sup>
Detroit	3	1.5	3,912,679	16.61	23.95	73.51	2.54	2.00
San Francisco	5	2.5	3,686,592	15.65	11.56	65.96	22.48	13.73
Seattle	13	6.6	3,366,824	14.29	3.99	87.83	8.18	2.96
Connecticut	8	9.0	3,287,116	13.96	8.34	86.99	4.67	6.48
Iowa	99	50.0	2,776,755	11.79	1.73	96.63	1.64	1.17
Atlanta	5	2.5	2,177,495	9.24	30.32	66.45	3.23	2.35
Utah	29	14.6	1,722,850	7.31	0.67	93.79	5.54	4.91
New Mexico	32	16.2	1,575,069	6.43	1.99	75.64	22.37	38.23
Hawaii	4	2.0	1,108,229	4.71	2.45	33.35	64.20	7.35

¶ % SEER Population = Percent of total SEER population at specific site.

§ % Black, % White, and % other races expressed as a percentage of total population at the geographic site.  
The following sites include 2% or more Asian/Pacific Islander population: San Francisco (16.26%) Seattle (5.55%), Atlanta (2.21%), Utah (1.95%), Hawaii (61.86%), New Mexico includes 8.86% American Indian/Eskimo population.

¥ May include persons also classified as white, black, or other races.

TABLE 2

## Comparison of Sociodemographic Factors for SEER vs Other U.S. Counties

Characteristic	All Counties			Counties with $\geq 5\%$ Black Population		
	SEER Counties	Non-SEER Counties	P-value	SEER Counties	Non-SEER Counties	P-value
<b>Socioeconomic Status<sup>¶</sup></b>						
Per Capita Income (\$1000)	20.8 (19.3, 22.4)	18.4 (17.9, 19.0)	<.001	23.1 (21.0, 25.5)	19.0 (18.3, 19.6)	<.001
% High School Completed of Age $\geq 25$ population	73.6 (70.8, 76.0)	66.2 (65.3, 67.2)	<.001	73.4 (69.5, 77.3)	65.3 (64.2, 66.5)	<.001
Unemployment Rate (%)	5.00 (4.39, 5.70)	5.71 (5.56, 5.85)	<.001	5.15 (4.23, 6.10)	5.59 (5.38, 5.81)	.01
Owner-Occupied Housing(%)	63.5 (61.0, 66.3)	64.3 (62.3, 66.5)	.23	60.7 (56.4, 64.0)	61.1 (58.5, 63.8)	.74
<b>Size of MSA (%)<sup>§</sup></b>						
$\geq 1$ million population	49.9	40.9		74.8	50.0	
250,000-<1 million	28.5	24.7		23.8	27.7	
100,000-<250,000	4.9	10.3	p<0.001	0	8.6	p<0.001
<100,000	2.6	1.3		1.3	0.6	
non-metropolitan (rural)	14.1	22.7		0	13.1	

¶ Values provided are weighted means with 95% Confidence Intervals

§ Chi-square test for trend.

TABLE 3

## Density of Physician Resources\*

Physician Resources†	All U.S. Counties			Counties with $\geq 5\%$ Black Population		
	SEER Counties	Non-SEER Counties	P-value	SEER Counties	Non-SEER Counties	P-value
Non-Federal MD's	241.5 (202.1, 282.9)	211.3 (195.2, 227.8)	.001	290.2 (234.5, 347.9)	247.2 (226.6, 270.0)	.01
General Practice MD's	25.4 (21.5, 29.5)	27.2 (26.3, 28.2)	.01	23.3 (18.0, 30.6)	26.1 (24.9, 27.4)	.01
Family Practice MD's	17.3 (14.4, 20.8)	18.5 (17.8, 19.4)	.05	15.3 (10.9, 21.6)	17.4 (16.5, 18.4)	.03
Medical Specialists	80.3 (64.4, 95.7)	67.8 (60.9, 74.2)	.001	101.9 (80.2, 125.2)	82.9 (74.4, 92.2)	.007
General Int Med MD's	34.4 (27.0, 41.5)	28.8 (25.5, 31.9)	<.001	44.5 (34.6, 56.0)	34.7 (30.8, 39.4)	.002
Board Certified Oncologists	3.5 (2.65, 4.19)	3.2 (2.95, 3.45)	.08	3.7 (3.01, 4.87)	3.9 (3.61, 4.30)	.42
Surgical Specialists	58.0 (49.7, 66.9)	52.2 (48.8, 56.0)	.01	69.1 (55.8, 82.5)	61.7 (56.8, 66.8)	.07
General Surgeons	15.6 (13.0, 18.1)	14.6 (13.5, 15.8)	.15	18.8 (15.1, 22.5)	17.2 (15.8, 19.1)	.21
Ob-Gyn MD's	13.4 (11.5, 15.4)	11.5 (10.7, 12.3)	<.001	16.1 (12.6, 19.3)	13.7 (12.7, 14.8)	.005
Radiation/Oncologists	1.3 (0.99, 1.54)	1.1 (0.97, 1.19)	.008	1.5 (1.18, 1.90)	1.3 (1.15, 1.46)	.06

\* Analyses weighted by total population of the county. P-values < 0.001 considered significant.

† All physician resources expressed as physicians per 100,000 population. Values provided are weighted means with 95% Confidence Intervals

TABLE 4

## Density of Hospital Resources\*

Characteristic	All Counties			Counties with $\geq 5\%$ Black Population		
	SEER Counties	Non-SEER Counties	P-value	SEER Counties	Non-SEER Counties	P-value
<b>Hospitals/Beds</b>						
Hosps with JCAH Accreditation	1.4 (1.30, 1.58)	1.7 (1.65, 1.81)	<.001	1.19 (1.09, 1.36)	1.53 (1.46, 1.63)	<.002
Hosps with Residency Training	0.5 (0.36, 0.57)	0.4 (0.35, 0.43)	.005	0.57 (0.46, 0.70)	0.49 (0.44, 0.54)	.10
Short-Term General Beds	341.7 (300.2, 376.5)	399.2 (382.8, 418.0)	<.001	354.8 (298.8, 411.0)	435.9 (412.1, 464.9)	<.001
Short-Term Community Beds	322.3 (282.3, 360.0)	379.6 (363.0, 398.9)	<.001	325.0 (270.8, 397.7)	411.0 (387.3, 439.6)	<.001
General Med/Surg Beds Setup	188.4 (163.1, 212.8)	227.9 (215.7, 239.5)	<.001	199.0 (160.9, 235.2)	249.8 (233.2, 269.3)	<.001
Veterans Administration Beds	24.0 (15.0, 35.1)	33.1 (28.4, 38.1)	.15	26.5 (15.4, 40.5)	40.75 (34.3, 48.2)	.18
<b>Hospital Facilities</b>						
Hospitals with:						
CT Scanner	1.21 (1.10, 1.31)	1.50 (1.42, 1.58)	<.001	1.08 (0.98, 1.21)	1.37 (1.29, 1.48)	.004
MRI Scanner	0.36 (0.28, 0.44)	0.37 (0.35, 0.40)	.69	0.33 (0.26, 0.40)	0.41 (0.37, 0.45)	.10
Radiation Therapy	0.42 (0.34, 0.49)	0.41 (0.38, 0.44)	.83	0.48 (0.39, 0.58)	0.47 (0.43, 0.50)	.77
Bone Marrow Transplantation	0.10 (0.06, 0.14)	0.07 (0.05, 0.08)	<.001	0.12 (0.06, 0.18)	0.09 (0.07, 0.11)	.12
Outpatient Surgery	1.69 (1.52, 1.93)	2.02 (1.91, 2.16)	.02	1.13 (1.02, 1.27)	1.63 (1.53, 1.76)	<.001
Home Health Services	0.65 (0.56, 0.80)	0.76 (0.71, 0.83)	.24	0.44 (0.34, 0.57)	0.59 (0.54, 0.67)	.09
Hospice Services	0.33 (0.26, 0.42)	0.34 (0.31, 0.37)	.88	0.27 (0.20, 0.36)	0.27 (0.23, 0.31)	.98

\*Analyses weighted by total population of the county. P-values <.001 considered significant. Values provided are weighted means with 95% Confidence Intervals.

## THE EFFECT OF LEGISLATIVE REQUIREMENTS ON THE USE OF BREAST-CONSERVING SURGERY

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### ABSTRACT

**Background** We studied the effect of state legislation requiring the disclosure of options for the treatment of breast cancer on the use of breast-conserving surgery in clinical practice.

**Methods** The National Cancer Institute's Surveillance, Epidemiology, and End Results registry provided data on women from 30 through 79 years of age who underwent breast-conserving surgery or mastectomy for local or regional breast cancer from 1983 through 1990. We examined the trend over time in the use of breast-conserving surgery among patients in four sites (Connecticut, Iowa, Seattle, and Utah) where there were no state laws specifically requiring the disclosure of options for the treatment of breast cancer by physicians. For four additional sites (Detroit, Atlanta, New Mexico, and Hawaii) that had such legislation, we determined whether the rate of breast-conserving surgery after the legislation was different from the expected rate.

**Results** An attorney rated the legislation as giving most direction to physicians in Michigan, followed by Hawaii, Georgia, and New Mexico. The rate of breast-conserving surgery was up to 8.7 percent higher than expected in Detroit for six months after the passage of the Michigan law ( $P < 0.01$ ). The rate was up to 13.2 percent higher than expected in Hawaii for 12 months after that state's law was passed ( $P < 0.05$ ) and up to 6.0 percent higher than expected in Atlanta for 3 months after the passage of the Georgia law ( $P < 0.01$ ). After these transient increases, the surgery rates reverted to the expected levels. No significant effect was detected in New Mexico, where only a resolution without legal force was passed.

**Conclusions** Legislation requiring physicians to disclose options for the treatment of breast cancer appeared to have only a slight and transient effect on the rate of use of breast-conserving surgery. (N Engl J Med 1996;335:1035-40.)

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**C**ONTINUING medical education, peer-review organizations, consensus conferences, and practice guidelines have been advocated as ways of improving the quality of medical care. However, evidence of their effectiveness is lacking.<sup>1-6</sup> Another way to change medical practice is through legislation that requires certain

actions on the part of health care providers. Traditionally, legislation of this type has been restricted to public health measures, such as the reporting of cases of infectious diseases, but more recently it has been applied to other kinds of medical issues, such as the care of patients with the acquired immunodeficiency syndrome. Several state laws have been passed with the aim of promoting breast-conserving surgery for women with breast cancer in an early stage. The enactment of such legislation provides an opportunity to examine the effectiveness of legislative mandates in altering medical practice.

By 1985, several randomized trials had demonstrated the efficacy of breast-conserving surgery,<sup>7-10</sup> but the use of this treatment in clinical practice increased only minimally during the late 1980s.<sup>11-13</sup> The slow adoption of breast-conserving surgery and the identification of nonclinical factors that affect its use (such as geographic location and the type of hospital)<sup>14,15</sup> raised the question whether all women with breast cancer are adequately informed about their therapeutic options.

By 1990, 18 states had passed laws specifically addressing the disclosure by physicians of options for the treatment of breast cancer.<sup>16</sup> We assessed the effect of such legislation on the use of breast-conserving surgery in clinical practice.

### METHODS

#### Sources of Data

The National Cancer Institute's Surveillance, Epidemiology, and End Results (SEER) registry data base<sup>17</sup> was the source of the clinical data we studied. The data were collected from nine geographically distinct, population-based tumor registries that include information on patients' demographic characteristics, the extent of disease, and initial treatment for approximately 10 percent of the patients with cancer in the United States. The sites in the SEER data base included the entire states of Connecticut, Hawaii, Iowa, New Mexico, and Utah and the metropolitan areas of Atlanta, Detroit, Seattle, and San Francisco and Oakland.

From the Departments of Medicine (A.B.N.), Biostatistics (R.G.H.), Bioethics (R.S.), and Family and Community Medicine (M.S.G.), Medical College of Wisconsin, Milwaukee, and the Department of Medicine, University of Texas Medical Branch, Galveston (J.S.G.). Address reprint requests to Dr. Nattinger at the Division of General Internal Medicine, Administrative Offices (FMLH-East), Medical College of Wisconsin, 9200 W. Wisconsin Ave., Milwaukee, WI 53226.

Because social and demographic factors affect the use of breast-conserving surgery,<sup>14,15,18</sup> we obtained information regarding the urban or rural character and the mean per capita income of the county in which each patient resided from the Area Resource File.<sup>19</sup>

Copies of the relevant state legislation were obtained from Westlaw, an on-line service provided by the West Publishing Company.

### Patients

Data on women were selected from the SEER data base if the patients were given a diagnosis of breast cancer between 1983 and 1990 and were residents of any SEER site other than San Francisco and Oakland, California. Patients from the San Francisco area were excluded because California enacted a statute related to the treatment of breast cancer in 1980, before the period we studied.

Of the 100,207 women initially considered for the analysis, 38,661 were excluded because they had advanced disease (19,466 women), because the cancer in the data base for the study period was not the patient's first cancer (13,767 women), because mastectomy or breast-conserving surgery was not performed (5973 women), because the woman was less than 30 years of age (685 women) or more than 79 (11,574 women) at the time of diagnosis, because the cancer was not confirmed histologically (1614 women), because the cancer was bilateral (135 women), or because there was no valid county code in the data base (33 women). Some patients were excluded for more than one reason. A total of 61,546 women met the criteria of the study.

### Definitions of Variables

Patients were categorized by the SEER program as treated with breast-conserving surgery if they underwent segmental mastectomy, lumpectomy, quadrantectomy, tylectomy, wedge resection, nipple resection, excisional biopsy, or partial mastectomy, either with or without axillary lymph-node dissection. All other patients underwent some form of complete mastectomy.

According to the conventions of the SEER program, the cancer was considered localized if it was confined to the breast tissue and regional if it had extended into surrounding tissue or regional lymph nodes. The patients were grouped according to their age at diagnosis (30 to 49 years, 50 to 64 years, or 65 to 79 years). Women were classified according to race as white, black, or "other." The mean per capita income in 1990 of the patient's county of residence and the size of the metropolitan statistical area in which the patient lived were obtained from the Area Resource File.

### Description and Ranking of Statutes

Without knowing the rates of use of breast-conserving surgery, an attorney summarized the relevant statutes and ranked them according to how much direction the laws gave physicians. The criteria included the legal requirements pertaining to the development and documentation of informed consent, as well as the inclusion of sanctions against physicians who failed to comply with the statute or protection for those who complied with it.

### Statistical Analysis

The period from 1983 through 1990 was broken into 32 three-month periods. The patients were assigned to periods according to the month of diagnosis. For Hawaii, where there were consistently fewer than 100 patients per three-month period, six-month periods were used. Logistic-regression models were used, with the dependent variable representing the receipt of breast-conserving surgery or mastectomy by individual patients.

Initially, we developed a model based on patients who lived at sites without relevant state laws regarding treatment for breast cancer (Connecticut, Iowa, Seattle, and Utah), in order to evaluate the trend over time in the use of breast-conserving surgery. The model included factors known to influence the use of breast-conserving surgery,<sup>13-15,18</sup> including age at diagnosis, race, stage of disease, SEER site, per capita income in the county, and size of

the metropolitan statistical area. The effect of time was modeled by allowing a unit step-function variable<sup>20</sup> to enter the model for each quarter from the second quarter of 1983 through the fourth quarter of 1990. This variable could increase or decrease the probability that a patient would undergo breast-conserving surgery, but it entered the model only during quarters when there were significant increases or decreases, as compared with the previous quarter, in the use of such surgery.

To test whether the trend over time was the same among the four SEER sites without relevant state laws, terms for the interactions of site with time and stage of disease with time were included in the model. A constant was also incorporated, allowing a different average base rate of use of breast-conserving surgery for each SEER site. The interaction of site with time was not significant at any site, indicating that the trend over time was essentially the same among the sites without state laws requiring the disclosure of treatment options.

We applied the model of the temporal trend to the sites at which a law requiring the disclosure of treatment options to patients had been enacted, in order to determine whether the rate of use of breast-conserving surgery in these sites differed from that expected from the temporal trend. After adjustment for the base-line use of breast-conserving surgery in each of the SEER sites, residual analysis<sup>21</sup> was used to identify which periods in the states with such laws deviated significantly from the temporal trend. This approach was used in preference to the simpler and more restrictive step-intervention model,<sup>20</sup> since the effect of the law could have been felt before the law's enactment (for example, because of publicity or debate about the law), the effect of the law could have been gradual or delayed (for example, if informational material was not immediately available), and the effect of the law could have been transient and have diminished over time.

We sought evidence of an effect of the law on the use of breast-conserving surgery by determining the rate of use of such surgery around the effective date of the law and assessing whether that rate differed significantly from the use predicted on the basis of the model for trend over time. To address the problem of making many statistical comparisons, we used the k-ratio multiple-comparisons procedure, extended to the regression case.<sup>22</sup> This procedure provides strong protection against the finding of a significant difference when there is primarily random variation and provides high sensitivity when there are many significant differences.

In line with our previous description of geographic variation in the use of breast-conserving surgery,<sup>14</sup> we found that adjustment was required for a significant effect of the site. We accomplished this by adjusting the y intercept of the temporal trend to fit the average of the first two quarters of 1983 (in the cases of Detroit, Atlanta, and New Mexico) or, in the case of Hawaii, to fit the overall average for the state, since its law was passed at the beginning of 1983.

## RESULTS

### The Study Cohort

Table 1 shows the characteristics of the study cohort. There was a trend toward increasing numbers of patients with breast cancer over time. The states of Connecticut, Iowa, Washington, and Utah had not enacted relevant laws by 1990; 35,853 women (58.3 percent) were residents of these states. The remaining 25,693 women (41.7 percent) were residents of Michigan, Hawaii, Georgia, or New Mexico.

### Laws Requiring Disclosure of Treatment Options

Of the four states included in the SEER registry that passed legislation or a resolution specifically pertaining to the disclosure of options for the treatment

**TABLE 1.** CHARACTERISTICS OF THE 61,546 WOMEN IN THE STUDY POPULATION.

CHARACTERISTIC	No. (%)
Age at diagnosis — yr	
30–49	16,165 (26.3)
50–64	22,155 (36.0)
65–79	23,226 (37.7)
Stage of disease	
Local	37,766 (61.4)
Regional	23,780 (38.6)
Race	
White	54,571 (88.7)
Black	4,214 (6.8)
Other	2,478 (4.0)
Unknown	283 (0.5)
Year of diagnosis	
1983	6,355 (10.3)
1984	6,696 (10.9)
1985	7,234 (11.8)
1986	7,732 (12.6)
1987	8,405 (13.7)
1988	8,438 (13.7)
1989	8,119 (13.2)
1990	8,567 (13.9)
SEER site*	
Atlanta	5,791 (9.4)
Connecticut	12,068 (19.6)
Detroit	13,474 (21.9)
Hawaii	2,911 (4.7)
Iowa	9,649 (15.7)
New Mexico	3,517 (5.7)
Seattle	10,570 (17.2)
Utah	3,566 (5.8)
Residence	
Metropolitan statistical area†	
≥1,000,000 people	25,518 (41.5)
250,000–1,000,000 people	21,143 (34.4)
100,000–250,000 people	3,263 (5.3)
<100,000 people	1,772 (2.9)
Nonmetropolitan (rural)	9,850 (16.0)
Received breast-conserving surgery	
Yes	14,522 (23.6)
No	47,024 (76.4)
<b>DOLLARS</b>	
Per capita income of county	
Median	20,139
10th percentile	15,339
90th percentile	26,884

\*SEER denotes the Surveillance, Epidemiology, and End Results program.

†The categories are those used by the Bureau of Health Professions.<sup>19</sup>

of breast cancer, Michigan had the statute<sup>23</sup> that was rated the most strongly directive, followed by Hawaii,<sup>24</sup> Georgia,<sup>25</sup> and New Mexico (in that state only a resolution without legal standing was passed).<sup>26</sup>

Michigan's law (enacted in 1986) requires physicians to inform patients with breast cancer orally and in writing about alternative methods of treatment. This statutory requirement may be satisfied by distributing a brochure developed by the state public health department or a different brochure that contains substantially the same information. The patient must sign a form indicating that she has received a

copy of the brochure, and this form is to be included in the patient's chart. The statute includes protection for physicians who comply with the law, but no specific sanctions against physicians who fail to comply. The statute explicitly states that a physician's duty to inform patients does not require the disclosure of information "beyond what a reasonably well-qualified physician would know."

The Hawaii statute (enacted in 1983) requires the Medical Examining Board to establish informed-consent standards for mastectomy. These standards must cover the substantive content of the information to be given to women for whom mastectomy is recommended (including recognized alternative treatments), the manner in which the information is to be given, and the manner in which the patient's consent is to be given. This statute does not include specific requirements for documentation or specific protection of or sanctions against physicians.

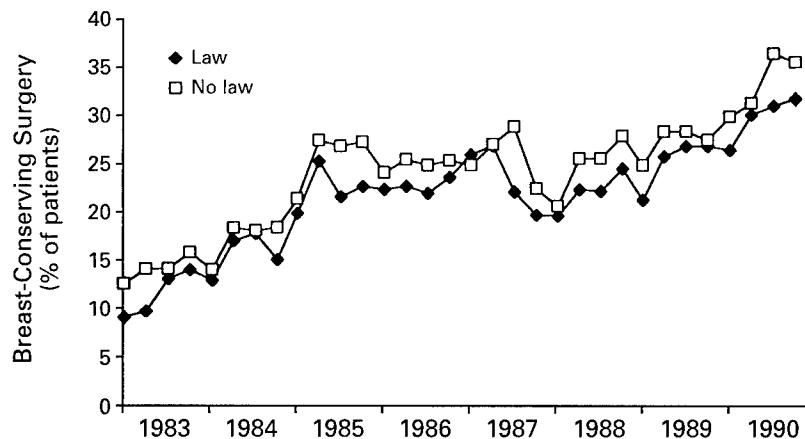
The Georgia statute (enacted in 1984) states that "when funds are specifically appropriated for such purpose," the Board of Medical Examiners is to publish and make available to physicians an informational booklet on treatments for breast cancer, and to urge them by letter to distribute a copy of the booklet to patients with breast cancer. Informed-consent standards are not addressed, and there are no requirements for documentation or protection and no sanctions for physicians.

New Mexico's legislature passed a resolution in 1984 that urged physicians to inform patients with breast cancer about options for treatment, using a brochure to be developed by the state health department, in conjunction with the medical societies and the University of New Mexico Medical School. Since this resolution had no force of law, it was considered the least directive.

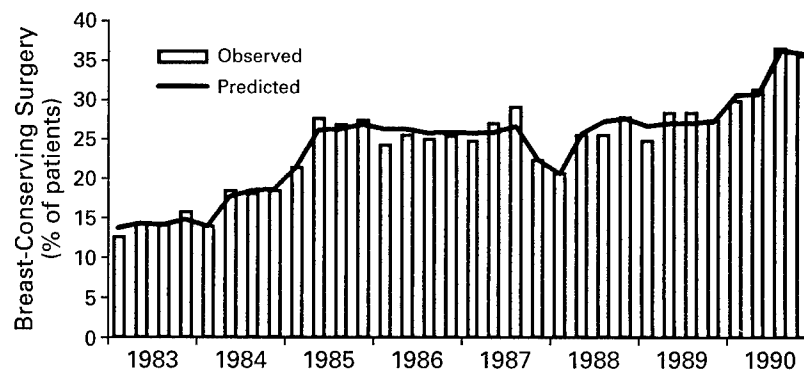
Pursuant to all the states' laws and the New Mexico resolution, an informational brochure detailing alternatives for the treatment of breast cancer was developed by each of these states.

#### Use of Breast-Conserving Surgery over Time

Figure 1 shows the use of breast-conserving surgery according to quarter, from 1983 through 1990, for women residing in the states with laws regulating the disclosure of alternative treatments for breast cancer and in the states without such laws. Logistic regression was used to model the trend over time in the use of breast-conserving surgery among patients residing in the sites without relevant laws. The logistic regression included terms for all the covariates shown in Table 1. Figure 2 depicts the observed rates of breast-conserving surgery in these sites and the rates predicted by the model. A chi-square test for lack of fit of the model was not significant ( $P=0.37$ ), indicating that the model was fitted adequately to the observed data. There was a gradual increase in



**Figure 1.** Use of Breast-Conserving Surgery for Local or Regional Breast Cancer in Four States with Laws Requiring the Disclosure of Treatment Options and in Four States with No Such Laws as of 1990. Data shown are unadjusted data from the registry of the Surveillance, Epidemiology, and End Results program.



**Figure 2.** Observed Rates of Breast-Conserving Surgery and Temporal Trends Predicted by the Logistic-Regression Model in Four States without Laws Requiring the Disclosure of Treatment Options. Data are from the registry of the Surveillance, Epidemiology, and End Results program.

the use of breast-conserving surgery from 1983 to 1985, followed by relative stability through mid-1990, with the exception of a dip in late 1987 and early 1988.

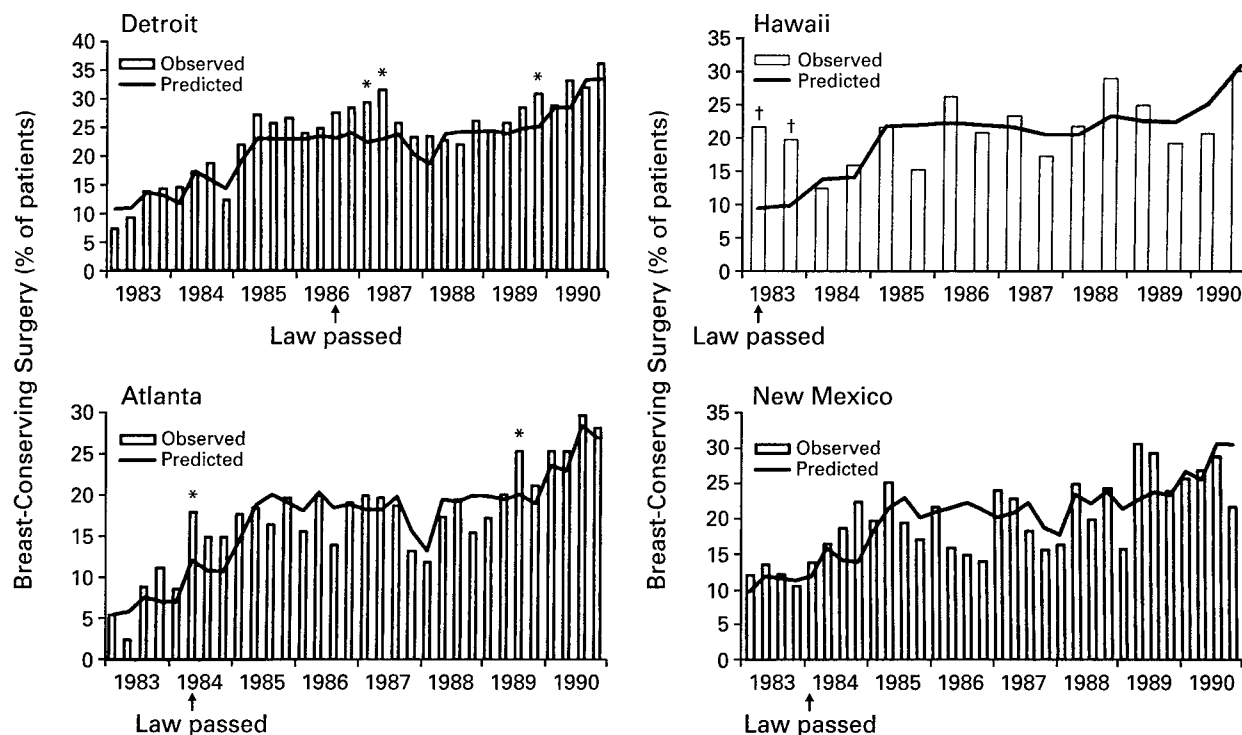
#### Use of Breast-Conserving Surgery at Sites with Relevant Laws

Figure 3 shows the observed rate of breast-conserving surgery in each of the sites with laws regarding the disclosure of options for treatment. Superimposed is the expected rate of breast-conserving surgery for each period, adjusted for the covariates in Table 1, according to the logistic-regression model of the trend over time.

The Michigan law took effect in July 1986, but physicians were not subject to the terms of the leg-

islation until November 1986, by which time the informational brochure had been published. The use of breast-conserving surgery in Detroit showed a small but steady increase from mid-1986 through mid-1987. The surgery was significantly more frequent than expected during the first half of 1987, reaching a maximum of 8.7 percent more use than expected (standard error, 2.4 percent). The rate of use of breast-conserving surgery was also higher than expected during the fourth quarter of 1989. Interestingly, in a different statute,<sup>27</sup> a program to reduce mortality due to breast cancer was established in Michigan in the third quarter of 1989. It included programs of professional education regarding breast-cancer screening, diagnosis, referral, treatment, and rehabilitation, as well as public education regarding





**Figure 3.** Observed Rates of Breast-Conserving Surgery at the Sites with Laws Requiring the Disclosure of Treatment Options, as Compared with the Rates Predicted on the Basis of the Trend over Time in Four Sites without Such Laws.

Data are from the registry of the Surveillance, Epidemiology, and End Results program. The asterisks indicate  $P < 0.01$  and daggers  $P < 0.05$  for the comparison of the observed and expected rates, after adjustment for multiple comparisons. The observed and expected rates did not differ significantly in New Mexico. Six-month periods were used in Hawaii, and three-month periods at the other sites.

the options available for the treatment of breast cancer, among other topics.

The Hawaii law was passed during the spring session of 1983 and was signed into law in June 1983. The Medical Examining Board's informed-consent guidelines for mastectomy were released on September 21, 1983. The rate of use of breast-conserving surgery in Hawaii was significantly higher than expected throughout 1983, reaching a maximum of 13.2 percent higher use than expected (standard error, 3.8 percent). The rate of use of breast-conserving surgery returned to the expected level by 1984.

The Georgia statute was signed into law on April 5, 1984, and went into effect on July 1, 1984. The informational brochure was published by late 1984. The rate of use of breast-conserving surgery was significantly higher than expected in Atlanta in the second quarter of 1984, with a maximum of 6.0 percent higher use than expected (standard error, 3.3 percent). The rate of use of breast-conserving surgery was also significantly higher than expected in the third quarter of 1989.

The New Mexico resolution was passed in February 1984, and the written brochure on alternatives for breast-cancer treatment was published by No-

vember 1984. There was some increase in the use of breast-conserving surgery over the expected level during the last six months of 1984, but the difference was not statistically significant.

## DISCUSSION

We found that state laws requiring the disclosure of alternatives for the treatment of breast cancer were temporally associated with slight increases (6 to 13 percent) in the use of breast-conserving surgery in the states with the most directive laws. The increases were transient, however, lasting from 3 to 12 months, after which the use of breast-conserving surgery reverted to the level expected on the basis of the trend in states without specific legislation.

Why was the apparent effect of these laws so small? The assumption underlying these statutes was that women with breast cancer were not being fully informed of their choices and that measures to increase the discussion of alternative treatments would lead to increases in the use of breast-conserving surgery. However, a major determinant of the choice of therapy appears to be the recommendation of the surgeon,<sup>28-31</sup> which would not be expected to be affected by the legislation. Also, research by Nayfield

et al.<sup>16</sup> suggests that only a minority of patients with cancer pursue a decision-making process that is enhanced by additional information; for some patients such information may complicate the process.<sup>31</sup>

A number of factors may explain the transient increases in breast-conserving surgery, which were temporally related to the passage of the laws we studied. It is possible that the laws did influence physicians to discuss alternative treatments. However, patients might have been more aware of these alternatives because of publicity surrounding the passage of the laws. If such publicity was important, increased public awareness could have spilled over into states without legislation, thereby affecting the use of breast-conserving surgery in those states as well. This process could explain the transient increases in the use of breast-conserving surgery in the states with relevant laws, because the effect in states without such legislation would have been incorporated into the model of the temporal trend in the use of breast-conserving surgery that we used to assess the effect of the laws.

Legislation to require specific clinical actions on the part of physicians is unusual. Critics of such legislation claim that it can introduce an adversarial component into the doctor-patient relationship by suggesting to the public that physicians must be coerced to behave appropriately.<sup>32,33</sup> Moreover, even in the absence of specific legislation, the development of the informed-consent doctrine in common law has established the legal requirement for full disclosure by physicians of alternative treatments. Many contend that such legislation should therefore be pursued only for compelling reasons, when the benefit of improved patient care clearly outweighs the potential harm to the physician-patient relationship. The lack of a clinically important or sustained effect of legislation designed to increase the use of breast-conserving surgery should serve as a warning against the passage of such legal requirements in the future.

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**RATES OF SURVEILLANCE TESTING AND OFFICE VISITS AFTER INITIAL TREATMENT FOR EARLY STAGE BREAST CANCER.** MM Schapira, TL McAuliffe, AB Nattinger, Division of General Internal Medicine and Division of Biostatistics, Medical College of Wisconsin, Milwaukee, WI.

The purpose of this study was to determine patterns of surveillance testing after initial treatment for early stage breast cancer. A data-base linking Medicare administrative claims to Surveillance, Epidemiology, and End Results (SEER) clinical data was obtained. Demographic, clinical and treatment elements were taken from the SEER data base. Insurance eligibility, office visits, radiology imaging procedures, and health provider specialty elements were taken from the Medicare claims data.

The study cohort consisted of 384 women aged 65 years and older diagnosed in 1985-86, treated with a lumpectomy or mastectomy, and alive 12 months after the initiation of treatment. Ninety-four percent of the cohort remained alive 24 months after treatment, and 88% remained alive 36 months after treatment. Women received an average of 1.8 chest radiographs per year, 0.89 mammograms per year, and 0.40 bone scans per year for 3 years. Eighty-eight percent had a chest radiograph claim in the initial testing period (first 6 months after treatment), 68% in the first surveillance year, and 63% in the second surveillance year. Seventy-eight percent had a mammogram in the initial testing period, 64% in the first surveillance year, and 59% in the second surveillance year. Forty-two percent had a bone-scan in the initial testing period, 25% in the first surveillance year, and 22% in the second surveillance year. On average, women had 8.4 physician office visits per year and 0.94 consultant visits per year. Of office visit claims in which specialty type was identified (65%), 39% were to Internal Medicine providers, 24% to Family Practice or General Practitioner providers, and 11% to General Surgery providers. In conclusion, claims data indicate low use of radiographic surveillance testing but high use of physician office visits in the 36 months after initial treatment for early stage breast cancer.

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20 Jun 00


MEMORANDUM FOR Administrator, Defense Technical Information  
Center, ATTN: DTIC-OCA, 8725 John J. Kingman  
Road, Fort Belvoir, VA 22060-6218

SUBJECT: Request Change in Distribution Statements

1. The U.S. Army Medical Research and Materiel Command has reexamined the need for the limitation assigned to technical reports written for Award Number DAMD17-94-J-4043. Request the limited distribution statement for Accession Document Numbers ADB225277, ADB235938, and ADB249595, be changed to "Approved for public release; distribution unlimited." These reports should be released to the National Technical Information Service.

2. Point of contact for this request is Ms. Virginia Miller at DSN 343-7327 or by email at Virginia.Miller@det.amedd.army.mil.

FOR THE COMMANDER:

  
PHYLLIS M. RINEHART  
Deputy Chief of Staff for  
Information Management